K091326

Section 6
510(K) Summary

MAY 27 2009

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date is May 5, 2009.

A. **Contact Information** [21 CFR 807.92(a)(1)].

ActivaTek Inc.
2734 S. 3600 West, Unit F
West Valley, UT 84120

Tel: 1-801-969-0883
Fax: 1-800-680-5520
Contact person: Jamal Yanaki

B. **Device Trade Name, Common Name, Classification** [21 CFR 807.92(a)(2)]

Trade Name: *ActivaPatch* Iontophoresis System

Device Common Name: Iontophoresis Patch Electrode

Classification Name: Iontophoresis, other uses

Product Code: EGJ

Panel: Physical Medicine

Device Classification: Class III

C. **Predicate Devices** [21 CFR 807.92(a)(3)]

The ActivaTek *ActivaPatch* Iontophoresis System uses the same materials as the following predicate device: *Trivarion* Buffered Iontophoresis Electrode System K061522 manufactured by ActivaTek, Inc.

The ActivaTek *ActivaPatch* Iontophoresis System uses similar technology and has equivalent physical output characteristics as the following predicate device: *Action Patch* Iontophoresis System K030395 manufactured by EMPI, Inc.

D. **Device Description** [21 CFR 807.92(a)(4)]

The ActivaTek *ActivaPatch* Iontophoresis System (Iontophoresis Patch) consists of a self-contained, disposable single-use iontophoresis patch, instructions for use, and an alcohol prep pad containing 70% isopropyl alcohol.

The Iontophoresis Patch consists of an electronic module, an LED indicator, an active electrode, and a return electrode. These elements are incorporated under an adhesive foam covering which adheres the device to the skin. Its dimensions are 5.7 inches (length), 3.4 inches (width), and 0.2 inches (thickness).

The Iontophoresis Patch is designed to deliver a calibrated and fixed half dose of 40 mAmp*minutes and a full dose of 80 mAmp*minutes.

The *ActivaPatch* Iontophoresis System sequence of operation is signaled by its LED.

a) The operator applies the *ActivaPatch* to the skin.
b) The operator then pulls the tab located on the outer surface of the patch.
c) In the Initial Skin Impedance Measurement Phase, the *ActivaPatch* measures voltage across the active and return electrodes to indicate the level of skin impedance. For high skin impedance, the LED flashes once every 4 seconds. This indicates that the skin impedance is too high for iontophoretic delivery. The treatment timer is not started. For moderate skin impedances, the LED flashes pulses four times every 30 seconds. The patch continues to monitor the skin impedance but does not turn on the treatment timer. When the skin impedance becomes optimal, the LED blinks once every 30 seconds. This indicates that the impedance is appropriate to start an iontophoretic treatment session and the *ActivaPatch* starts the treatment timer.
d) In the First Half Dose Delivery Phase, the *ActivaPatch* LED continues to blink once every 30 seconds. This phase lasts 80 minutes and delivers an ionic dosage of 40 mA*minutes. At the end of the First Half Dose Delivery, the LED blinks short-long-short sequences every 30 seconds for 3 minutes. This signals to the user that the transition to the Second Half Dose Delivery Phase has begun.
e) During the Second Half Dose Delivery Phase, the *ActivaPatch* LED blinks two pulses every 30 seconds. During this final phase, another 40 mA*minute dose is delivered. At the end of the delivery, the power in the device is automatically shut off and the LED does not blink.
f) If at any time the skin impedance increases to high levels (e.g., the electrode falls off of the skin site) the *ActivaPatch* goes into the Skin Measurement Phase and the LED flashes pulses once every 4 seconds. The treatment timer is suspended and restarts when the skin impedance falls to optimal levels.

E. **Device Specification** [21 CFR 807.92(a)(6)]

The *ActivaPatch* Iontophoresis System delivers a calibrated half dose of 40 mAmp and a full dose of 80 mAmps. It operates with a voltage of 6V.

F. **Indications for Use** [21 CFR 807.92(a)(5)]

The ActivaTek *ActivaPatch* Iontophoresis System is intended to be used for the administration of soluble salts into the body for medical purposes and as an alternative to hypodermic injection.

G. **Conclusion** [21 CFR 807.92(a)(3)]

Technologically, the ActivaTek *ActivaPatch* Iontophoresis System was found to be substantially equivalent to the currently cleared EMPI Action Patch (K030395) and ActivaTek *Trivarion* Buffered Iontophoresis Electrode (K061522). The indications are identical to the previously cleared EMPI *Action Patch* (K030395). We believe that there are no new questions of safety or efficacy raised by the introduction of the ActivaTek *ActivaPatch* Iontophoresis System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

ActivaTek, Inc.
% Mr. Jamal Yanaki
President & CEO
2734 S. 3600 W. Unit F
Salt Lake City, Utah 84119

Re: K091326
Trade/Device Name: ActivaTek ActivaPatch Iontophoresis System
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: III
Product Code: EGJ
Dated: May 3, 2009
Received: May 9, 2009

Dear Mr. Yanaki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the device as described below. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, there are concerns relating to the fact that no drug is currently labeled for administration via an iontophoresis device. The Agency currently is evaluating this public health concern regarding the safety and effectiveness of this route of administration of drugs, and in the near future will inform manufacturers of certain additional steps the Agency believes are necessary to address this concern.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-0120.

Also, please not the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5
Indications for Use

510(k) Number (if known): K091326

Device Name: ActivaTek *ActivaPatch* Iontophoresis System

Indications for Use:

The ActivaTek *ActivaPatch* Iontophoresis System is intended to be used for the administration of soluble salts into the body for medical purposes and as an alternative to hypodermic injection.

Prescription Use___X____
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091326